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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,698	04/26/2005	Nicolai Agger	P07181US00	8742
22885 7590 07/27/2007 MCKEE, VOORHEES & SEASE, P.L.C. 801 GRAND AVENUE SUITE 3200 DES MOINES, IA 50309-2721			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,698

Applicant(s)

AGGER, NICOLAI

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-23 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11 and 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 10 May 2007 with the cancellation of Claims 3, 4 24 and 25, and newly amended claims 1, 2, 5, 9-13, 17 and 21-23.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1, 2 and 5-23 are currently pending.

This application contains claim 12 drawn to an invention nonelected without traverse in "Applicant Arguments/Remarks Made in an Amendment" filed on 10/12/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 2, 5-11 and 13-23 are currently under examination.

Claim Objections

Claims 1, 2 and 5 are objected to because of the following informalities: "at least one carbohydrate and electrolytes" in line 5 of claim 1 and line 5 of claim 2 should be corrected to read "at least one carbohydrate and further comprising electrolytes" or "at least one carbohydrate and an electrolytes" or "at least one carbohydrate and at least one electrolytes". The term "claims" in line 1 should be corrected to read "claims". Appropriate correction is required. Newly applied as necessitated by amendment.

Claim 2 is objected to because of the following informalities: It is unclear if Applicant is intending to claim a method of using the composition or a method of making since Applicant recites a method of making a composition and then recites a method of using a composition. These claims (a method of making a composition and a method of using a composition) should be separated into a method of making a composition and a method of using a composition. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-11 and 13-23 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to provide prior support or antecedent basis for the language "A composition for treatment of gastrointestinal disorders of monogastric animals" in claim 1, "feeding the prepared composition to animals" in claim 2, "a mixture of at least one carbohydrate and electrolyte" in claims 1 and 2, and "derived from" in line 2 of claim 9 and failing to comply with the written description requirement. Newly applied as necessitated by amendment.

The claim as set forth in the amendment filed 05/10/2007 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the instant case, the original Claim 1 did

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not disclose "A composition for treatment of gastrointestinal disorders of monogastric animals" in claim 1, "feeding the prepared composition to animals" in claim 2, "a mixture of at least one carbohydrate and electrolyte" in claims 1 and 2, or "derived from" in line 2 of claim 9, wherein Applicant claimed, as Claim 1, "A composition comprising: from 5-30% by weight of Isphagula Husk, and from 1-20% by weight of at least one amino acid, and from 20-80% by weight of at least one carbohydrate and electrolytes for use as a therapeutical agent", "Use of a composition comprising: from 5-30% by weight of Isphagula Husk, from 1-20% by weight of at least one amino acid, and from 20-80% by weight of at least one carbohydrate and electrolytes for the preparation of a medicament for simultaneous or sequential use in treating a state of disorder on the intestinal system of monogastric animals, including human beings" as claim 2, and "A composition according to claim 1, wherein the at least one amino acid is comprised in the soluble components of lactic yeast" as claim 9. In the amended Claim 1, Applicant claims, "A composition for treatment of gastrointestinal disorders of monogastric animals comprising: from 5-30% by weight of Isphagula Husk (*Plantago ovata*), and from 1-20% by weight of at least one amino acid, and from 20-80% by weight of a mixture of at least one carbohydrate and electrolytes", thereby introducing an intended use (for treatment of gastrointestinal disorders of monogastric animals) not previously presented in the claims or that has support in the specification, and a mixture not previously disclosed in the claims or in the specification, wherein both of these new limitations are considered to be new matter, in the amended Claim 2, Applicant claims, "A method of treating gastrointestinal disorders of monogastric animals comprising: preparing a composition

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of from 5-30% by weight of Isphagula Husk (*Plantago ovata*), from 1-20% by weight of at least one amino acid, and from 20-80% by weight of a mixture of at least one carbohydrate and electrolytes and feeding the prepared composition to animals", thereby introducing a method of treating gastrointestinal disorders of monogastric animals, which was not previously disclosed in the claims or in the specification, a mixture not previously disclosed in the claims or in the specification, and a step of feeding the prepared composition to animals, which was not previously disclosed in the claims or in the specification, and all of these new limitations are considered to be new matter, and in the amended Claim 9, Applicant claims, "The composition according to claim 1, wherein the at least one amino acid is derived from the soluble components of lactic yeast.", thereby introducing that the amino acid is derived from soluble components of lactic yeast, whereas before it appears Applicant was claiming that the lactic yeast comprised at least one amino acid, hence these are completely different claimed inventions and the new limitation disclosed in claim 9 is considered to be new matter.

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept for the method, mixture, or source of amino acids as now claimed by Applicant. Applicant discloses that, "The preparation is for use as a therapeutical agent, such as for use in treating a state of disorder in the intestinal system of monogastric animals,

including humans. A state of disorder in the intestinal system is in particular all intestinal disorders in which the epithelial layer is damaged, mostly as a result of malabsorption diarrhoea, also associated with dehydration" on page 1, lines 13-22 and lines 24-26 of the specification as originally filed, "It is an object of the invention to provide an improved preparation for the treatment of monogastric animals, including human beings, suffering from diarrhoea, in particular to provide an improved healing of the mucosa during diarrhoea. It is an object of the present invention to provide an improved preparation for the restoration of the epithelium layer of the intestines. It is an object of the present invention to provide an improved preparation for supplying nutrients to the epithelium layer of the intestines in an improved way. It is an object of the present invention to provide an improved preparation for supplying nutrients to a monogastric animal, including human beings, suffering from diarrhoea, in particular a young animal. It is an object of the present invention to provide a preparation for enhanced cell growth, especially for the cells of the intestinal epithelium. It is an object of the present invention to provide a preparation for use as a therapeutical agent" (See lines 14-31 on page 6 continued onto page 7, lines 1 and 2). Applicant further discloses examples of compositions having the above disclosed effect, however, none of these compositions appear to contain a mixture of a carbohydrate and an electrolyte (See page 1, lines 3-22, page 7, lines 6-31, page 8, lines 29 and 30, page 9, lines 1-12, page 12, lines 30 and 31 and page 13, lines 1-7). Finally, Applicant further discloses "A mixture of amino acids according to the invention may be provided from lactic yeast ("Milchhefe") that has been processed to provide the soluble components of the yeast cells. The process may

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be either, or a combination of, the following processes: plasmolysis, autolysis, thermolysis or mechanical disruption. The processed lactic yeast is preferably supplemented with glutamine. The lactic yeast mixture is preferred as a source of amino acids due to a relatively high content of amino acids in an inexpensive and readily available product. The indicative value of the content of amino acids in a lactic yeast mixture is 48-52% by weight. In theory, any cells which may be subjected to the processes mentioned above may be processed and used as a source of amino acids" on page 9, lines 14-24. This is not sufficient support for the new genus: "A composition for treatment of gastrointestinal disorders of monogastric animals", "A method of treating gastrointestinal disorders of monogastric animals comprising: preparing a composition of from 5-30% by weight of Isphagula Husk (*Plantago ovata*), from 1-20% by weight of at least one amino acid, and from 20-80% by weight of a mixture of at least one carbohydrate and electrolytes and feeding the prepared composition to animals" or "The composition according to claim 1, wherein the at least one amino acid is derived from the soluble components of lactic yeast.". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

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As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-11 and 13-23 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All rejections newly applied as necessitated by amendment.

The metes and bounds of Claims 1 and 2 are rendered uncertain by the phrase "A composition for treatment of gastrointestinal disorders of monogastric animals comprising: from 5-30% by weight of Isphagula Husk (*Plantago ovata*), and from 1-20% by weight of at least one amino acid, and from 20-80% by weight of a mixture of at least one carbohydrate and electrolytes" and "A method of treating gastrointestinal disorders of monogastric animals comprising: preparing a composition of from 5-30% by weight of Isphagula Husk (*Plantago ovata*), from 1-20% by weight of at least one amino acid, and from 20-80% by weight of a mixture of at least one carbohydrate and electrolytes and feeding the prepared composition to animals" because it is unclear what Applicant means by "gastrointestinal disorders of monogastric animals". The lack of clarity renders

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the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 9 recites the limitation "the soluble components of lactic yeast" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 10 May 2007, with respect the rejection of claims 1, 5-8, 10, 11, 13, 16-19 and 22 under 35 U.S.C. 102(b) as being anticipated by Bell et al. (A*, US 6,365,176 B1) have been fully considered and are persuasive. The rejection of claims 1, 5-8, 10, 11, 13, 16-19 and 22 under 35 U.S.C. 102(b) as being anticipated by Bell et al. (A*, US 6,365,176 B1) has been withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Newly amended claims 1, 5, 11, 13, 17, 21 and 23 and claims 6-8, 10, 14-16 and 18-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gjerlov (B*, US Patent Number 5,038,396), in view of Simone (C*, US Patent Number 5,397,786).

This rejection is maintained for reasons of record set forth in the paper mailed on 3 November 2006 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 10 May 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Gjerlov teaches a preparation for rehydrating monogastric animals, including human beings, suffering from diarrhea (please note that diarrhea is a gastrointestinal disorder of monogastric animals), wherein the composition comprises electrolytes, such as sodium chloride and potassium chloride (See column 3, lines 54-55), in an amount of 40-60% by weight (See column 4, lines 3 and 33), fibre (which is an alternative spelling of fiber) from dried, crushed seed coats of *Plantgo ovata*, which is synonymous with Isphagula Husk (See column 4, lines 22-26 and lines 42-66), in an amount of 20-70% by weight (See column 4, lines 31 and 32), fillers, such as fibrous wheat bran (See column 12, claims 8 and 9), taste corrigents and coloring agents (See abstract), such as pharmaceutically tolerable coloring agents (See column 3, line 63) in the form of a beverage (See column 5, lines 26-49). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

Simone teaches a rehydration drink for people who work under severe conditions, are athletes and patients who exhibit dehydration from diarrhea or vomiting, comprising 1-35 milligrams of at least one carbohydrate, such as glucose (See column

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2, lines 45-48, 64 and 65), electrolytes in an amount of 2 to 2500 milligrams, such as sodium chloride and potassium chloride (See column 3, lines 5 and 9), at least one ammonia neutralizer, in the form of an amino acid, in an amount of 0.1 to 750 milligrams, such as glutamine (See column 3, lines 21-28), and at least one antioxidant, such as vitamin E (See Abstract). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

The teachings of Gjerlov are set forth above. Gjerlov does not teach a composition comprising Isphagula husk, at least one amino acid, at least one carbohydrate and electrolytes. Nor does Gjerlov teach a composition further comprising glutamine, glucose, or alpha tocopherol. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Gjerlov to provide the instantly claimed invention because at the time the invention was made, a composition for rehydrating monogastric animals, including human beings, suffering from diarrhea, comprising electrolytes, such as sodium chloride and potassium chloride, Isphagula Husk, fillers, such as fibrous wheat bran, taste corrigents and coloring agents, such as pharmaceutically tolerable coloring was known, as clearly taught by Gjerlov, as was a rehydration drink for people suffering from diarrhea comprising carbohydrates, such as glucose, electrolytes, such as sodium chloride and potassium chloride, amino acids, such as glutamine, and at least one antioxidant, such as vitamin E , as clearly taught by Simone.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition, to combine Isphagula husk, at least one amino acid, at least one carbohydrate and electrolytes and further comprising glutamine, glucose, at least one filler, at least one taste corrigent and at least one coloring agent to provide the instantly claimed composition because at the time the invention was made, a composition for rehydrating monogastric animals, including human beings, suffering from diarrhea, comprising electrolytes, such as sodium chloride and potassium chloride, Isphagula Husk, fillers, such as fibrous wheat bran, taste corrigents and coloring agents, such as pharmaceutically tolerable coloring as was known as clearly taught by Gjerlov, as was a rehydration drink for people suffering from diarrhea comprising carbohydrates, such as glucose, electrolytes, such as sodium chloride and potassium chloride, amino acids, such as glutamine, and at least one antioxidant, such as vitamin E, as clearly taught by Simone. Therefore, it would have been obvious to one of ordinary skill in the art to modify the composition taught by Gjerlov to include the ingredients of the composition taught by Simone to provide the instantly claimed invention at the time the invention was made since both compositions were known to rehydrate humans suffering from diarrhea.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that it is *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the

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same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and to mix carbohydrates and electrolytes together and then add them to a composition because the order of the method steps do not matter provided that the final product as disclosed in the art is the same as that claimed by Applicant. (See MPEP § 2111.01(I)). Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues that prior art cited by the Examiner for § 102 is rendered moot by the amendments to the claims because none of the claims disclose compositions for treatment of gastrointestinal disorders that contain the low amounts of Isphagula Husk

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(*Plantago ovata*) and yet achieve the desired benefits. Applicant further argues that as a result, the claims containing those low amounts, 5-30%, are not suggested by the art and it is surprising that it works at such levels when, for the example, the reference Gerlov shows 40-43%.

However this is not found persuasive for the reasons set forth above and for the reasons of record, particularly since diarrhea is a gastrointestinal disorder of monogastric animals. Therefore, the rejection is maintained

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
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Amy L. Clark
July 12, 2007


MICHELE FLOOD
PRIMARY EXAMINER